

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA AB, and AMYLIN
PHARMACEUTICALS, LLC

Plaintiffs,

V.

C.A. No. 14-1478-GMS

TEVA PHARMACEUTICALS USA,
INC.

Defendant

TEVA PHARMACEUTICALS USA,
INC.

Counterclaim-Plaintiff,

V.

ASTRAZENECA PHARMACEUTICALS LP
and AMYLIN PHARMACEUTICALS, LLC

Counterclaim-Defendants

**PLAINTIFFS ASTRAZENCA PHARMACEUTICALS LP AND AMYLIN
PHARMACEUTICALS, LLC'S ANSWER TO TEVA'S COUNTERCLAIMS**

Plaintiffs and Counterclaim-Defendants AstraZeneca Pharmaceuticals LP

(“AstraZeneca”), and Amylin Pharmaceuticals, LLC (“Amylin”) (collectively “Plaintiffs”), by their attorneys, hereby reply to Defendant/Counterclaim-Plaintiff Teva Pharmaceuticals USA Inc.’s (“Teva” or “Defendant”) counterclaims contained in “Teva Pharmaceuticals USA, Inc.’s Answer, Affirmative Defenses, and Counterclaims,” dated January 19, 2015 (“Counterclaims”).

NATURE OF THE ACTION

1. To the extent any of Teva's Answers to paragraphs 1–70 of Plaintiffs' Complaint are determined in whole or in part to state counterclaims or the basis for counterclaims, Plaintiffs incorporate by reference paragraphs 1–70 of their Complaint and deny each and every additional allegation contained in Teva's Answer, except to the extent admitted in Plaintiffs' responses to Teva's Counterclaims paragraphs 1–58 below. To the extent any of Teva's Separate Defenses are determined to state counterclaims, each and every one of the allegations contained therein is denied, except to the extent admitted in Plaintiffs' responses to Teva's Counterclaims paragraphs 1–58 below. To the extent any of Teva's Response to Plaintiffs' Request for Relief subparagraphs (A) to (H) are determined to state counterclaims, each and every one of the allegations contained therein is denied, except to the extent admitted in Plaintiffs' responses to Teva's Counterclaims paragraphs 1–58 below.

2. The allegations of paragraph 2 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Teva purports to state a cause of action for declaratory judgment, but deny that there is any factual or legal basis for the declaratory judgment action or that Teva is entitled to the relief it seeks.

PARTIES

3. On information and belief, Plaintiffs admit the allegations of paragraph 3.
4. Plaintiffs admit the allegations of paragraph 4.
5. Plaintiffs admit the allegations of paragraph 5.

JURISDICTION AND VENUE

6. The allegations of paragraph 6 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Teva purports to state a cause

of action for declaratory judgment, but deny that there is any factual or legal basis for the declaratory judgment action or that Teva is entitled to the relief it seeks. Plaintiffs do not contest that this Court has subject matter jurisdiction over this action. Plaintiffs deny the remaining allegations of paragraph 6.

7. The allegations of paragraph 7 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest the Court's exercise of jurisdiction for purposes of this action. Plaintiffs deny the remaining allegations of paragraph 7.

8. The allegations of paragraph 8 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that venue is proper in this action. Plaintiffs deny the remaining allegations of paragraph 8.

FACTUAL BACKGROUND

9. Plaintiffs admit the allegations of paragraph 9.

10. Plaintiffs admit the allegations of paragraph 10.

11. Plaintiffs admit the allegations of paragraph 11.

12. Plaintiffs admit the allegations of paragraph 12.

13. Plaintiffs admit the allegations of paragraph 13.

14. Plaintiffs admit the allegations of paragraph 14.

15. Plaintiffs are without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 15 and therefore deny those allegations.

16. Plaintiffs admit that on October 31, 2014, Plaintiffs received a Paragraph IV Notice Letter from Defendant Teva USA indicating that Teva USA had submitted to FDA ANDA No. 205984 with a Paragraph IV certification, seeking approval to engage in the commercial manufacture, use or sale of Teva USA's ANDA Products prior to the expiration of

the '576, '700, '026, '744 and '423 patents and two other patents. Plaintiffs further admit that Teva's Paragraph IV Notice Letter asserted that '576, '700, '026, '744 and '423 patents were either invalid or would not be infringed by Teva's ANDA products. Plaintiffs otherwise deny the allegations in paragraph 16.

17. Plaintiffs admit the allegations of paragraph 17.

18. The allegations of paragraph 18 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the '576, '700, '026, '744 and '423 patents are listed in the Orange Book with respect to Byetta®. Plaintiffs admit that Teva sent a Notice Letter concerning Teva USA's filing of ANDA No. 205984 with a Paragraph IV certification regarding at least the '576, '700, '026, '744 and '423 patents. Plaintiffs admit that there exists a controversy between Plaintiffs and Teva USA, redressable by judgment of this Court, as to the infringement of the '576, '700, '026, '744 and '423 patents and the validity of claims of those patents. Plaintiffs deny the remaining allegations of paragraph 18.

Count I
Declaratory Judgment of Non-Infringement
United States Patent No. 6,858,576

19. Plaintiffs repeat and reassert all responses to paragraphs 1-18 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 19.

20. The allegations of paragraph 20 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '576 patent. Plaintiffs deny the remaining allegations of paragraph 20.

21. Plaintiffs deny the allegations of paragraph 21.

22. Plaintiffs deny the allegations of paragraph 22.

Count II
Declaratory Judgment of Non-Infringement
United States Patent No. 6,872,700

23. Plaintiffs repeat and reassert all responses to paragraphs 1-22 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 23.

24. The allegations of paragraph 24 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '700 patent. Plaintiffs deny the remaining allegations of paragraph 24.

25. Plaintiffs deny the allegations of paragraph 25.

26. Plaintiffs deny the allegations of paragraph 26.

Count III
Declaratory Judgment of Non-Infringement
United States Patent No. 6,956,026

27. Plaintiffs repeat and reassert all responses to paragraphs 1-26 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 27.

28. The allegations of paragraph 28 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '026 patent. Plaintiffs deny the remaining allegations of paragraph 28.

29. Plaintiffs deny the allegations of paragraph 29.

30. Plaintiffs deny the allegations of paragraph 30.

Count IV
Declaratory Judgment of Non-Infringement
United States Patent No. 6,902,744

31. Plaintiffs repeat and reassert all responses to paragraphs 1-30 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 31.

32. The allegations of paragraph 32 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '744 patent. Plaintiffs deny the remaining allegations of paragraph 32.

33. Plaintiffs deny the allegations of paragraph 33.

34. Plaintiffs deny the allegations of paragraph 34.

Count V
Declaratory Judgment of Non-Infringement
United States Patent No. 7,521,423

35. Plaintiffs repeat and reassert all responses to paragraphs 1-34 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 35.

36. The allegations of paragraph 36 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '423 patent. Plaintiffs deny the remaining allegations of paragraph 36.

37. Plaintiffs deny the allegations of paragraph 37.

38. Plaintiffs deny the allegations of paragraph 38.

Count VI
Declaratory Judgment of Invalidity
United States Patent No. 6,858,576

39. Plaintiffs repeat and reassert all responses to paragraphs 1-38 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 39.

40. The allegations of paragraph 40 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '576 patent and Teva's allegations that the '576 patent is invalid. Plaintiffs deny the remaining allegations of paragraph 40.

41. Plaintiffs deny the allegations of paragraph 41.

42. Plaintiffs deny the allegations of paragraph 42.

Count VII
Declaratory Judgment of Invalidity
United States Patent No. 6,872,700

43. Plaintiffs repeat and reassert all responses to paragraphs 1-42 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 43.

44. The allegations of paragraph 44 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '700 patent and Teva's allegations that the '700 patent is invalid. Plaintiffs deny the remaining allegations of paragraph 44.

45. Plaintiffs deny the allegations of paragraph 45.

46. Plaintiffs deny the allegations of paragraph 46.

Count VIII
Declaratory Judgment of Invalidity
United States Patent No. 6,956,026

47. Plaintiffs repeat and reassert all responses to paragraphs 1-46 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 47.

48. The allegations of paragraph 48 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '026 patent and Teva's allegations that the '026 patent is invalid. Plaintiffs deny the remaining allegations of paragraph 48.

49. Plaintiffs deny the allegations of paragraph 49.

50. Plaintiffs deny the allegations of paragraph 50.

Count IX
Declaratory Judgment of Invalidity
United States Patent No. 6,902,744

51. Plaintiffs repeat and reassert all responses to paragraphs 1-50 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 51.

52. The allegations of paragraph 52 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '744 patent and Teva's allegations that the '744 patent is invalid. Plaintiffs deny the remaining allegations of paragraph 52.

53. Plaintiffs deny the allegations of paragraph 53.

54. Plaintiffs deny the allegations of paragraph 54.

Count X
Declaratory Judgment of Invalidity
United States Patent No. 6,902,744

55. Plaintiffs repeat and reassert all responses to paragraphs 1-54 as if they were incorporated herein. Plaintiffs deny any remaining allegations of paragraph 55.

56. The allegations of paragraph 56 contain legal conclusions to which no response is required. Count X refers at times to the '744 patent and at times to the '423 patent. To the extent Count X and paragraph 56 refer to the '744 patent, as stated in paragraphs 52-54, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '744 patent and Teva's allegations that the '744 patent is invalid. To the extent Count X and paragraph 56 refer to the '423 patent, Plaintiffs do not contest that there is a case or controversy between Plaintiffs and Teva as to Teva's infringement of the '423 patent and Teva's allegations that the '423 patent is invalid. Plaintiffs deny the remaining allegations of paragraph 56.

57. Count X refers at times to the '744 patent and at times to the '423 patent. To the extent paragraph 57 refers to the '744 patent, Plaintiffs deny the allegations of paragraph 57. To the extent paragraph 57 refers to the '423 patent, Plaintiffs deny the allegations of paragraph 57.

58. Count X refers at times to the '744 patent and at times to the '423 patent. To the extent paragraph 58 refers to the '744 patent, Plaintiffs deny the allegations of paragraph 58. To the extent paragraph 58 refers to the '423 patent, Plaintiffs deny the allegations of paragraph 58.

AFFIRMATIVE DEFENSES

In response to Teva's counterclaims, and without admitting any allegations of the Counterclaims not otherwise admitted, Plaintiffs assert the following affirmative and other

defenses. In asserting these defenses, Plaintiffs do not assume the burden of proof with respect to any issue upon which applicable law places the burden of proof upon Teva.

First Affirmative Defense

Teva's counterclaims, in whole or in part, fail to state claims upon which relief can be granted.

Second Affirmative Defense

Counterclaims, in whole or in part, are non-justiciable.

Third Affirmative Defense

Plaintiffs have not knowingly or intentionally waived any applicable affirmative defense and reserve the right to assert and rely upon such other affirmative defenses as may become available or apparent during discovery proceedings. Plaintiffs further reserve the right to amend their Answer and/or their affirmative defenses accordingly, and/or to delete affirmative defenses that Plaintiffs determine during the course of subsequent discovery are not applicable.

RESPONSE TO TEVA'S PRAYER FOR RELIEF

The remaining allegations of Teva's Counterclaims consist of Teva's Request for Relief, which contains conclusions of law for which no response is required. To the extent a response is required, Plaintiffs deny that Teva is entitled to any relief as sought in its Counterclaims.

WHEREFORE, Plaintiffs therefore respectfully request the following relief:

- (1) A judgment dismissing with prejudice Teva's Counterclaims and each Request For Relief contained therein;
- (2) An award to Plaintiffs of their costs and expenses in this action;
- (3) A judgment including each and every Request for Relief sought by Plaintiffs in the Complaint; and

(4) Such further and additional relief as this Court deems just and proper.

DATED: February 9, 2015

MCCARTER & ENGLISH, LLP

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